

**Notice of Allowability**

Application No.

09/971,773

Examiner

Robert M. Kelly

Applicant(s)

KANDA ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/21/05.
2. ☒ The allowed claim(s) is/are 69-80.
3. ☒ The drawings filed on 12 August 2004 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>03302005</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>8/12/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                              | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|   | 9. <input type="checkbox"/> Other _____  |

***Information Disclosure Statement***

It is noted that the Furukawa reference on the IDS of 8/12/05 was not previously submitted with the advisory action of 3/21/05. Such reference is now provided, and is signed on the basis of the explained relevance as per the amendment after final rejection filed 2/2/05.

***Priority***

The objection to Applicant's claimed priority is now withdrawn in light of the certified copies of the English translations of (1) the PCT/JP01/08804 document, filed by Applicant on 12/28/04; and (2) the Japanese patent application No. 2000-308526, filed 12/27/04. Further, the receipt of the official copies of these same two Japanese language documents is acknowledged, as they were submitted on 8/12/04.

***Claim objections/rejections***

The objections and rejections of the claims are withdrawn in light of the following Examiner's amendment.

**EXAMINER'S AMENDMENT**

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 30 March 2005, Mr. Sadoff requested an extension of time for two MONTH(S) and authorized the Director to charge Deposit Account No. 14-1140 the required fee of \$450.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

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by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

It is noted that the after-final amendments of 17 December 2004 and 2 February 2005 were not entered, and therefore, the last set of pending claims is the set of 12 October 2004. Accordingly, Claims 1-34, 36-60, 61, and 63-68 are presently pending.

The application has been amended as follows:

IN THE CLAIMS:

1. Claims 1-34, 36-60, 61, and 63-68 are cancelled.

2. Claims 69-80 are newly added as follows:

69. An isolated fucosyltransferase knock-out host cell wherein when a gene encoding an antibody molecule is introduced in to said host cell, said host cell produces an antibody composition comprising the antibody molecule,

said host cell being a mammalian cell,

said antibody molecule comprising a Fc region comprising complex N-glycoside-linked sugar chains bound to the Fc region,

said sugar chains comprising a reducing end which contains an N-acetylglucosamine, wherein the sugar chains do not contain fucose bound to the 6 position of N-acetylglucosamine in the reducing end of the sugar chains.

70. The isolated host cell of claim 69, wherein said host cell is a CHO cell.
71. The isolated host cell of claim 69, wherein said host cell is a NS0 cell.
72. The isolated host cell of claim 69, wherein said host cell is a SP2/0 cell.
73. The isolated host cell of claim 69, wherein said host cell is a YB2/0 cell.
74. The isolated host cell of claim 69, wherein said antibody molecule is an IgG antibody.
75. An isolated fucosyltransferase knock-out host cell comprising a gene encoding an antibody molecule, wherein said host cell produces an antibody composition comprising the antibody molecule,  
said host cell being a mammalian cell,  
said antibody molecule comprising a Fc region comprising complex N-glycoside-linked sugar chains bound to the Fc region,  
said sugar chains comprising a reducing end which contains an N-acetylglucosamine, wherein the sugar chains do not contain fucose bound to the 6 position of N-acetylglucosamine in the reducing end of the sugar chains.
76. The isolated host cell of claim 75, wherein said host cell is a CHO cell.

77. The isolated host cell of claim 75, wherein said host cell is a NS0 cell.
78. The isolated host cell of claim 75, wherein said host cell is a SP2/0 cell.
79. The isolated host cell of claim 75, wherein said host cell is a YB2/0 cell.
80. The isolated host cell of claim 75, wherein said antibody molecule is an IgG antibody.

IN THE TITLE:

3. The title has been rewritten as follows:

Cells producing antibody compositions with increased antibody dependent cytotoxic activity.

*Reasons for Allowance*

The following is an examiner's statement of reasons for allowance:

Applicant's claims no longer encompass encompass enzymes relating to the modification of a complex N-glycoside-linked sugar chain in which fucose is bound to the 6-position of N-Acetylglucosamine, and thus overcomes the written description rejection of 11/03/04.

Applicant's claims now no longer embrace the myriad of deletions of the FUT8 gene, thereby overcoming the enablement rejection of 11/03/04. Specifically, the claims now embrace

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a mammalian host cell with a knock out, which, when a gene is introduced to express antibodies, the glycosylated antibodies produced do not comprise fucose bound to the 6 position of N-Acetyl-glucoseamine at the reducing end of the glycosylations. Hence, at least one working embodiment has been demonstrated, and the composition is enabled.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### *Conclusion*

Claims 69-80 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.  
Examiner, USPTO, AU 1632  
2C55 Remsen Building  
(571) 272-0729

ANNE M. WEHBE PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', is written below the printed name and title.